



## Complete Summary

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### **GUIDELINE TITLE**

Chronic wounds of the lower extremity.

### **BIBLIOGRAPHIC SOURCE(S)**

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: chronic wounds of the lower extremity. Arlington Heights (IL): American Society of Plastic Surgeons; 2007 May. 21 p. [132 references]

### **GUIDELINE STATUS**

This is the current release of the guideline.

### **\*\* REGULATORY ALERT \*\***

### **FDA WARNING/REGULATORY ALERT**

**Note from the National Guideline Clearinghouse (NGC):** This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [July 08, 2008, Fluoroquinolones \(ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin\)](#): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

### **COMPLETE SUMMARY CONTENT**

**\*\* REGULATORY ALERT \*\***

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

## SCOPE

### DISEASE/CONDITION(S)

Chronic wounds of the lower extremity, including vascular (e.g., arterial, venous, or mixed ulcers), pressure ulcers, and neuropathic (e.g., diabetic ulcers)

### GUIDELINE CATEGORY

Evaluation  
Management  
Treatment

### CLINICAL SPECIALTY

Dermatology  
Family Practice  
Plastic Surgery  
Surgery

### INTENDED USERS

Advanced Practice Nurses  
Health Care Providers  
Physician Assistants  
Physicians

### GUIDELINE OBJECTIVE(S)

To conduct a systematic review of existing scientific literature addressing the assessment and treatment of chronic wounds of the lower extremity and to develop recommendations that fairly reflect current accepted medical standards

### TARGET POPULATION

Patients with chronic wounds of the lower extremity

### INTERVENTIONS AND PRACTICES CONSIDERED

#### Assessment

1. Medical history and physical exam
2. Assessment for venous insufficiency, using physical findings, Doppler ultrasonography, Duplex scanner plethysmography and venography
3. Assessment for arterial occlusive disease (history and ankle brachial index [ABI])
4. Assess for comorbidities of diabetes
5. Assess history and characteristics of wound, including evaluation for infection
6. Assess for confounding factors, allergies, osteomyelitis, remote or systemic infection, and comorbid risk factors

7. Assess pain, functional status, and quality of life
8. Regular follow-up

### **Treatment/Management**

1. Debridement
2. Pressure relief
3. Infection control
4. Management of exudate
5. Management of complications, including osteomyelitis and infection
6. Measures to prevent recurrence, including patient education, therapeutic modalities, and exercise programs

### **MAJOR OUTCOMES CONSIDERED**

Not stated

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

#### **Literature Search and Admission of Evidence**

This study was carried out using a prospective systematic method for identifying and evaluating current literature on the treatment of chronic wounds of the lower extremities. To identify relevant literature, a comprehensive search of the following databases was performed: OVID, Medline, CINAHL, Embase, the Cochrane Wounds Group database within the Cochrane Collaboration Library, the Agency for Healthcare Research and Quality (AHRQ) Clinical Practice Guidelines, and the National Guideline Clearinghouse.<sup>TM</sup> Additionally, the World Wide Web was searched using meta-search engines for national and international guidelines. The search term combination captured the concept "practice-guidelines AND wound" using a wide range of indexing terms, free text words and word variants. Search limits restricted results to English-language manuscripts.

Articles were selected if they met the following criteria: guideline, systematic review, consensus statement, care protocol, or healthcare technology assessment produced by national or international professional organizations and societies or governmental agencies; subject: comprehensive management of wounds of the lower extremity. From this list, key articles were identified and corresponding bibliographies hand searched for citations and manuscripts relevant to clinical questions about patient assessment, treatment, follow-up and prevention of wound recurrence.

Excluded from the search were articles that specifically addressed assessment and treatment of patients with burn wounds of the lower extremity, patients whose wounds were surgically closed, and patients with uncomplicated wounds that heal by primary intention (matrix deposition, contraction, and epithelialization).

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

### **Evidence Rating Scale for Diagnostic Studies**

<b>Level of Evidence</b>	<b>Qualifying Studies</b>
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

### **Evidence Rating Scale for Prognostic Studies**

<b>Level of Evidence</b>	<b>Qualifying Studies</b>
I	High-quality, multi-centered or single-centered, prospective cohort study with adequate power; or a systematic review of these studies
II	Lesser-quality prospective cohort study; retrospective study; untreated controls from a randomized controlled trial; or a systematic review of these studies
III	Case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

### **Evidence Rating Scale for Therapeutic Studies**

<b>Level of Evidence</b>	<b>Qualifying Studies</b>
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or a systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or a systematic review of these studies
III	Retrospective comparative study; case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

### **Critical Appraisal of the Literature**

Relevant articles were categorized by study type: randomized controlled trial, systematic review, cohort study, and case-control study. Each article was critically appraised for study quality according to criteria referenced in key publications on evidence-based medicine. Depending on type (prognostic, diagnostic, or therapeutic) and quality of study, each article was assigned a corresponding level of evidence according to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scales (see "Rating Scheme for the Strength of the Evidence" above), which were modified from scales developed by other surgical specialties and authorities on evidence-based medicine.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

### **Development of Clinical Practice Recommendations**

Practice recommendations were developed through critical appraisal of the literature and consensus of the American Society of Plastic Surgeons (ASPS) Health Policy Committee. Recommendations are based on the strength of supporting evidence and were graded according to the ASPS Grades of Recommendation Scale (see "Rating Scheme for the Strength of the Recommendations" below), which was modified from scales used by other surgical specialties and authorities in the practice of evidence-based medicine.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preference.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V; little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Approved by the Executive Committee of the American Society of Plastic Surgeons, May 2007

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Definitions for the levels of evidence for diagnostic, prognostic, and therapeutic studies (I–V) and the strength of the recommendations (A–D) are provided at the end of the "Major Recommendations" field.

Recommendations for Patient Assessment	Supporting Evidence	Grade
General	Expert Opinion	D

Recommendations for Patient Assessment	Supporting Evidence	Grade
<p>Medical History:</p> <ul style="list-style-type: none"> <li>Assess comorbidities, medications, allergies, and family history</li> </ul> <p>Physical exam:</p> <ul style="list-style-type: none"> <li>Assess cardiovascular status (pulse, blood pressure)</li> <li>Perform focused examination of the legs</li> </ul>		
<b>Venous Insufficiency</b>		
<p>Historical findings suggestive of venous insufficiency include:</p> <ul style="list-style-type: none"> <li>Prior history of thrombophlebitis, venous thromboembolism, and/or deep vein thrombosis</li> <li>History of symptomatic varicosities during pregnancy</li> <li>Surgical history of lower extremity trauma, vascular injury or previous varicose vein surgery</li> <li>Hypercoagulable states (e.g., cancer, infection, Factor VIII excess)</li> </ul>	(Baker et al., 1991; Berard et al., 2002; Blomgren et al., 2001; Labropoulos et al., "Patterns," 2007; Fink et al., 2002; Dajani et al., 1988)	<b>B</b>
<p>Physical findings suggestive of venous insufficiency include:</p> <ul style="list-style-type: none"> <li>Edema</li> <li>Wound presentation as shallow ulcer in the lower third of leg</li> <li>Venous dermatitis</li> <li>Lipodermatosclerosis</li> <li>Varicose veins</li> </ul>	(Blomgren et al., 2001; Labropoulos et al., "Patterns," 2007; Wong, Duncan, & Nichols, 2003)	<b>B</b>
<p>Diagnostic Tests:</p> <ul style="list-style-type: none"> <li>Doppler ultrasonography</li> <li>Duplex scanner plethysmography and venography</li> </ul>	(Shami et al., 1993; Alguire & Mathes, 1997; Wong, Duncan, & Nichols, 2003; Baxter & Polak, 1993)	<b>B</b>
Determine severity of venous insufficiency	Expert Opinion	<b>D</b>
<b>Arterial Occlusive Disease</b>		

<b>Recommendations for Patient Assessment</b>	<b>Supporting Evidence</b>	<b>Grade</b>
<p>Assess for a history of arterial occlusive disease:</p> <ul style="list-style-type: none"> <li>• Arterial peripheral vascular disease</li> <li>• Ischemic complaints</li> <li>• Rest pain</li> </ul>	(Wipke-Tevis et al., 2000; Dormandy & Murray, 1991; Jelnes et al., 1986; Criqui et al., 1985; Marston et al., 2006; Hiatt, Hoag, & Hamman, 1995; Khan et al., 2006; Wang et al., 2005; Henke et al., 2005)	<b>B</b>
<p>Assess for factors suggestive of arterial compromise:</p> <ul style="list-style-type: none"> <li>• Cold, pale feet (in warm environment)</li> <li>• Shiny, taut skin</li> <li>• Dependent rubor</li> <li>• Punched out appearance of ulcer</li> </ul>	(Khan et al., 2006)	<b>B</b>
<p>Diagnostic Tests:</p> <ul style="list-style-type: none"> <li>• Ankle brachial index (ABI)</li> <li>• If &lt;0.8, referral to specialist may be necessary to assess for arterial occlusive disease</li> </ul>	(Baxter & Polak, 1993; Dormandy & Murray, 1991; Jelnes et al., 1986; Stoffers et al., 1997; Marston et al., 2006; Hiatt, Hoag, & Hamman, 1995; Khan et al., 2006; de Vries et al., 2006; Ouwendijk et al., 2005)	<b>B</b>
<p>Determine severity of arterial occlusive disease:</p> <ul style="list-style-type: none"> <li>• ABI 0.6 to 0.8, suggestive of peripheral arterial occlusive disease</li> <li>• ABI &lt;0.5, suggestive of critical ischemia</li> <li>• ABI &gt;1.2, suggestive of calcification and noncompressibility of arterial wall</li> <li>• Consider vascular intervention or reconstruction</li> <li>• Contrast arteriography (or magnetic resonance angiography)</li> <li>• Refer to vascular specialist, if needed</li> </ul>	(Marston et al., 2006; O'Meara et al., 2000)	<b>B</b>
<p><b>Diabetes</b></p> <ul style="list-style-type: none"> <li>• Assess for comorbidities (microangiopathy, neuropathy, impaired immune response)</li> <li>• Assess for sensory derangement</li> </ul>	(Marston et al., 2006; Hiatt et al., 1995; Pham et al., 2000; Abbott et al., 1998; Yasuhara et al., 2002)	<b>B</b>

<b>Recommendations for Patient Assessment</b>	<b>Supporting Evidence</b>	<b>Grade</b>
(e.g., Semmes-Weinstein)		
<b>History and Characteristics of the Wound</b>		
Document history of the wound: <ul style="list-style-type: none"> <li>• Date and site(s) current ulceration began</li> <li>• Date and site(s) of previous ulcers</li> <li>• Prior duration to heal</li> <li>• Length of prior disease-free interval(s)</li> <li>• Prior treatments</li> <li>• Past surgical history of venous operation</li> <li>• Use of compression garments</li> </ul>	Expert Opinion	<b>D</b>
Document characteristics of the wound: <ul style="list-style-type: none"> <li>• Size</li> <li>• Nature of wound base tissue</li> <li>• Amount of drainage</li> </ul>	(Marston et al., 2006; O'Meara et al., 2000)	<b>B</b>
Evaluate wound for evidence of infection <ul style="list-style-type: none"> <li>• Necrotic tissue</li> <li>• Purulent drainage</li> <li>• Odor</li> <li>• Induration</li> <li>• Cellulitis</li> </ul>	(Cutting, 1998; Gardner et al., 2001)	<b>B</b>
For atypical and/or recalcitrant wounds, rule out other, less common causes of ulceration (biopsy may be necessary) <ul style="list-style-type: none"> <li>• Rheumatoid arthritis</li> <li>• Sickle cell disease</li> <li>• Pyogenic gangrenosum</li> <li>• Tumors (squamous cell and basal cell carcinomas)</li> </ul>	(Labropoulos et al., "Uncommon leg ulcers," 2007)	<b>B</b>
<b>Additional Considerations:</b>		
Assess for confounding factors: <ul style="list-style-type: none"> <li>• Impaired tissue perfusion (heart disease, obesity)</li> <li>• Tissue hypoxia</li> <li>• Metabolic disturbances (diabetes,</li> </ul>	(Wipke-Tevis et al., 2000; Jelles et al., 1986; Khan et al., 2006; O'Meara et al., 2000)	<b>B</b>

<b>Recommendations for Patient Assessment</b>	<b>Supporting Evidence</b>	<b>Grade</b>
nephropathy) <ul style="list-style-type: none"> <li>• Impaired healing</li> <li>• Immunosuppression</li> <li>• Tobacco use</li> <li>• Infection (systemic and local)</li> <li>• Nutrition and overall state of health</li> </ul>		
Assess and document allergies	(Saap et al., 2004; Lim et al., 2007; Tavadia et al., 2003; Machet et al., 2004)	<b>B</b>
Assess for the presence of osteomyelitis: <ul style="list-style-type: none"> <li>• Bone exposed (or easily probed)</li> <li>• Tissue necrosis overlying bone</li> <li>• Gangrene</li> <li>• Persistent sinus tract</li> <li>• Underlying open fracture</li> <li>• Underlying internal fixation</li> <li>• Wound recurrence</li> </ul> Osteomyelitis evaluation: <ul style="list-style-type: none"> <li>• Radiographic studies (plain radiographs, nuclear bone scan and/or magnetic resonance imaging)</li> <li>• If radiographic findings suggestive osteomyelitis, consider histologic evaluation and bone biopsy culture</li> </ul>	(Shih, Shih, & Wong, 2005; Senneville et al., 2006)	<b>B</b>
Determine the presence of remote site or systemic infection (septicemia, endocarditis, prosthesis infection):  Anatomic risk factors include: <ul style="list-style-type: none"> <li>• Prosthetic heart valve</li> <li>• Acquired cardiac valvular dysfunction</li> <li>• Cardiac malformation</li> <li>• Hypertrophic cardiomyopathy</li> <li>• Orthopedic prosthesis</li> <li>• Central nervous system (CNS) shunts</li> <li>• Nearby arteriovenous fistula</li> </ul>	(El-Ahdab et al., 2005)	<b>B</b>
Comorbid risk factors:	(El-Ahdab et al., 2005)	<b>B</b>

<b>Recommendations for Patient Assessment</b>	<b>Supporting Evidence</b>	<b>Grade</b>
<ul style="list-style-type: none"> <li>History of bacterial endocarditis</li> <li>Immune compromised or suppressed host</li> <li>Colonization, multi-drug resistant organisms</li> </ul>		
<b>Pain, Functional Status, and Quality of Life</b> <ul style="list-style-type: none"> <li>Assess pain level (Visual Analog Scale)</li> <li>Validated questionnaires can assess functional status and quality of life</li> </ul>	Expert Opinion	<b>D</b>

<b>Recommendations for Treatment</b>	<b>Supporting Evidence</b>	<b>Grade</b>
<b>Debridement:</b> <ul style="list-style-type: none"> <li>Excise all necrotic, infected, and poorly vascularized soft tissue</li> <li>May be necessary to perform serially</li> <li>Contraindicated in cases of gangrene or stable, dry, ischemic wound (evaluation of vascular status needed)</li> <li>Sharp debridement not recommended if vasculitis or pyoderma gangrenosum is suspected</li> <li>Following debridement, consider irrigation with saline</li> <li>If tissue is suspect for malignancy, perform biopsy and submit for histopathologic analysis</li> </ul>	(Thow & Smith, 2003; Smith, 2002; Granick et al., 2007)	<b>B</b>
<b>Pressure Relief</b> <ul style="list-style-type: none"> <li>Implement established repositioning schedule</li> <li>Head of the bed should be maintained at lowest possible level consistent with medical condition</li> <li>Use pressure-reducing devices</li> </ul>	(Duby et al., 1993; Cullum et al., 2001; Cullum et al., 2004)	<b>B</b>
<b>Infection Control</b>	(Gentry et al., 1989; White, Cutting, &	<b>B</b>

Recommendations for Treatment	Supporting Evidence	Grade
<ul style="list-style-type: none"> <li>Determine presence of invasive pathogens (culture and susceptibility testing of deep tissue sample; clinical presentation of induration, erythema, warmth, suppuration, and pain or tenderness)</li> <li>If infection is confirmed or highly suspect, prescribe appropriate antimicrobial intervention (oral cephalosporins, amoxicillin-clavulanic acid, macrolides, anti-staphylococcal penicillins, and fluoroquinolones can be used; however, no evidence supports superiority of one over the others)</li> <li>When determining the need for antibiotic treatment, consider risk of antibiotic resistance</li> <li>For mild to moderate infections, consider surgical debridement and narrow-spectrum antibacterials</li> <li>Wound infections that are severe and/or complicated by critical limb ischemia often necessitate hospitalization, parenteral broad-spectrum antibiotics, and surgical intervention</li> </ul>	Kingsley, 2006; Nelson et al., 2006; Vermeulen et al., 2005; O'Meara et al., 2000; Vermeulen et al., 2007)	
<b>Management of Exudate</b> <ul style="list-style-type: none"> <li>Maintain moist environment</li> <li>Remove soluble factors detrimental to wound healing</li> <li>Use appropriate dressings (available evidence shows no superiority in dressing materials)</li> <li>Consider classic dressings (gauze, foam, hydrocolloid, hydrogels)</li> <li>Consider bioactive dressings (topical antimicrobials, bioengineered composite skin equivalent, bilaminar dermal regeneration template, recombinant human growth factor)</li> </ul>	(Embil et al., 2000; Vermeulen et al., 2005; O'Meara et al., 2000; Vermeulen et al., 2007; Bergin & Wraight, 2006; Jones & Nelson, 2007)	<b>B</b>

Recommendations for Management of Complications	Supporting Evidence	Grade
<b>Osteomyelitis</b> <ul style="list-style-type: none"> <li>Consider aggressive resection of infected bone</li> <li>Implement culture-directed antibiotic</li> </ul>	(Henke et al., 2005; Bach et al., 2007; Eren, Ghofrani, & Reifenrath, 2001; Embil et al., 2006; Freeman et al., 2007)	<b>B</b>

<b>Recommendations for Management of Complications</b>	<b>Supporting Evidence</b>	<b>Grade</b>
therapy <ul style="list-style-type: none"> <li>• Use well-perfused tissue (typically muscle) for coverage</li> </ul>		
<b>Antibiotic Prophylaxis</b> <ul style="list-style-type: none"> <li>• Routine use of systemic antimicrobials not recommended for prevention of osteomyelitis, bacterial endocarditis, or prosthesis infection</li> <li>• Endocarditis prophylaxis is indicated for high risk patients undergoing dermatologic procedures on visibly inflamed or infected wounds</li> </ul>	(Henke et al., 2005)	<b>B</b>

<b>Recommendations for Follow-up</b>	<b>Supporting Evidence</b>	<b>Grade</b>
<b>Patient with Chronic Wounds:</b> <ul style="list-style-type: none"> <li>• Perform follow-up every month during wound healing</li> <li>• Assess for systemic infection</li> <li>• Assess pain, discuss pain reduction methods, and adjust pain medication accordingly</li> </ul>	Expert Opinion	<b>D</b>
<b>Patients with Venous Insufficiency:</b> <ul style="list-style-type: none"> <li>• During wound healing, weekly follow-up may be necessary</li> <li>• After wound healing, follow-up can be performed every 3 to 6 months, depending on patient, comorbidities, and patient's ability for self care</li> <li>• Patients with worsening symptoms may require more aggressive follow-up regimen</li> <li>• Perform physical exam of lower extremities (note changes in condition, skin color, temperature, tone, and hair, and presence of swelling; note new areas of skin breakdown or maceration)</li> <li>• Order additional diagnostic studies (venous duplex, venography) as indicated</li> </ul>	(Baker et al., 1991; Berard et al., 2002; Blomgren et al., 2001)	<b>B</b>
<b>Patients with Peripheral Arterial Disease:</b> <ul style="list-style-type: none"> <li>• Assess activity level, pain, changes in skin</li> </ul>	(Stoffers et al., 1997; Stein et al., 2006)	<b>B</b>

Recommendations for Follow-up	Supporting Evidence	Grade
temperature and color; inspect skin, pulses and capillary refill of the toes <ul style="list-style-type: none"> <li>Obtain ABI, which may indicate angiography</li> <li>If necessary, refer to vascular surgeon or interventional radiologist</li> </ul>		
<b>Patients with Diabetes:</b> <ul style="list-style-type: none"> <li>Physical exam should include assessment of comorbidities (presence of bone infections, peripheral vascular disease, neuropathy, and multiple recurrences)</li> <li>Evaluate patient's blood sugars, diet, and exercise</li> <li>Assess skin for pressure points, ischemic changes, and skin maceration</li> <li>Check prosthetics or shoes for abnormal wear</li> <li>Assess for peripheral vascular disease (ABI &lt;0.08)</li> <li>Assess for osteomyelitis</li> <li>Order laboratory studies (glycated hemoglobin [HbA1c], fasting glucose, lipid profile)</li> <li>If patients have increase risk for or have diabetic neuropathy, assess for friction or pressure injuries</li> <li>Patients with diabetic neuropathy should be seen every 3 months for assessment of skin trauma and early breakdown</li> <li>Assess for chronic pain and consider referral to pain specialist</li> </ul>	(Dormandy & Murray, 1991; Jelnes et al., 1986; Pham et al., 2000; Dolan et al., 2002)	<b>B</b>
<b>Patients with History of Osteomyelitis:</b> <ul style="list-style-type: none"> <li>Perform follow-up every month during wound healing</li> <li>Perform follow-up every 3-6 months to evaluate for recurrence of osteomyelitis</li> <li>Evaluate lower extremities to determine need for further tests</li> <li>Consider laboratory studies (erythrocyte sedimentation rate [ESR], C-reactive protein [CRP])</li> <li>Consider x-rays, magnetic resonance imaging (MRI), or bone scans, depending on symptoms</li> </ul>	Expert Opinion	<b>D</b>

<b>Recommendations for Prevention of Recurrence</b>	<b>Supporting Evidence</b>	<b>Grade</b>
<b>Patient Education:</b> <ul style="list-style-type: none"> <li>• Long-term nature of condition</li> <li>• Signs/symptoms of recurrence</li> <li>• Skin care (soaps, moisturizers, protective measures)</li> </ul>	Expert Opinion	<b>D</b>
<b>Therapeutic Modalities:</b> <ul style="list-style-type: none"> <li>• For patients with venous hypertension or risk for venous insufficiency, consider Graduated Compression Stockings</li> <li>• For patients with wounds in pressure point areas, consider off-loading devices, pressure dispersing surfaces</li> <li>• For patients with wounds secondary to abnormal sensitivity or mobility, consider repositioning and support surfaces</li> </ul>	(Duby et al., 1993; Cullum et al., 2001; Cullum et al., 2004; Cullum et al., "Compression for venous leg ulcers," 2000; Nelson, Bell-Syer, & Cullum, 2000; Cullum et al., "Compression bandages," 2000; Ibegbuna et al., 2003; Zajkowski et al., 2002)	<b>B</b>
<b>Exercise Programs Improve:</b> <ul style="list-style-type: none"> <li>• Patient mobility</li> <li>• Joint movement</li> </ul>	Expert Opinion	<b>D</b>

### **Definitions:**

### **Scale for Grading Recommendations**

<b>Grade</b>	<b>Descriptor</b>	<b>Qualifying Evidence</b>	<b>Implications for Practice</b>
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preference.
C	Option	Levels II, III, or IV evidence, but findings are	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds

Grade	Descriptor	Qualifying Evidence	Implications for Practice
		inconsistent	on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V; little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

### Evidence Rating Scale for Diagnostic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

### Evidence Rating Scale for Prognostic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, prospective cohort study with adequate power; or a systematic review of these studies
II	Lesser-quality prospective cohort study; retrospective study; untreated controls from a randomized controlled trial; or a systematic review of these studies
III	Case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

### Evidence Rating Scale for Therapeutic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled

Level of Evidence	Qualifying Studies
	trial with adequate power; or a systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or a systematic review of these studies
III	Retrospective comparative study; case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate treatment and management of chronic wounds of the lower extremity

### POTENTIAL HARMS

- Overuse of antibiotics for uncomplicated soft tissue infections risks tangible harm by promoting antimicrobial resistance.
- There is a risk of contact dermatitis following the use of topical antibiotics.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

Debridement is contraindicated in the presence of dry gangrene or a stable, dry ischemic wound until vascular status is evaluated. If vasculitis or pyoderma gangrenosum is suspected, sharp debridement is not recommended.

## QUALIFYING STATEMENTS

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- Clinical practice guidelines are strategies for patient management and are developed to assist physicians in clinical decision making. This guideline, based on a thorough evaluation of the scientific literature and relevant clinical experience, describes a range of generally acceptable approaches to diagnosis, management, or prevention of specific diseases or conditions. This guideline attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.
- However, this guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all circumstances presented by the patient, the available diagnostic and treatment options, and other available resources.
- This guideline is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance, and as practice patterns evolve. This guideline reflects the state of knowledge current at the time of publication. Given the inevitable changes in the state of scientific information and technology, periodic review, updating and revision will be done.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better  
Living with Illness

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: chronic wounds of the lower extremity. Arlington Heights (IL): American Society of Plastic Surgeons; 2007 May. 21 p. [132 references]

**ADAPTATION**

Not applicable: The guideline was not adapted from another source.

**DATE RELEASED**

2007 May

**GUIDELINE DEVELOPER(S)**

American Society of Plastic Surgeons - Medical Specialty Society

**SOURCE(S) OF FUNDING**

American Society of Plastic Surgeons

**GUIDELINE COMMITTEE**

Health Policy Committee of the American Society of Plastic Surgeons

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Not stated

**FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

**GUIDELINE STATUS**

This is the current release of the guideline.

**GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [American Society of Plastic Surgeons Web site](#).

Print copies: Available from the American Society of Plastic Surgeons, 444 East Algonquin Road, Arlington Heights, IL 6005-4664

**AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

- Description and development of evidence-based practice guidelines. American Society for Plastic Surgeons. Electronic copies: Available from the [American Society of Plastic Surgeons Web site](#).

Print copies: Available from the American Society of Plastic Surgeons, 444 East Algonquin Road, Arlington Heights, IL 6005-4664

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI Institute on October 15, 2007. The information was verified by the guideline developer on October 23, 2007. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

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